UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

EBONIA ELLIOTT-LEWIS, Plaintiff, v. ABBOTT LABORATORIES, INC., Defendant.	)	Civil Action No. 14-13155-PBS

MEMORANDUM AND ORDER

November 6, 2019

Saris, C.J.

INTRODUCTION

Plaintiff Ebonia Elliott-Lewis brings this civil action pro se against her former employer, Defendant Abbott Laboratories, Inc. ("Abbott"). She claims Abbott terminated her in retaliation for raising internal concerns about the company's off-label marketing and pre-approval promotion of its products. She alleges retaliation under the False Claims Act ("FCA") and wrongful termination in violation of public policy. Both parties have moved for summary judgment on the two claims.

After hearing, the Court **ALLOWS** Abbott's motion for summary judgment (Docket No. 159) and **DENIES** Plaintiff's motion for summary judgment (Docket No. 164).

FACTUAL BACKGROUND

The following facts are undisputed except where otherwise stated.

I. Hiring and Expense Reporting Investigation

Plaintiff joined Abbott Vascular, a division of Abbott, in 2010 as a medical science manager ("MSM") assigned to the northeastern United States. As an MSM, Plaintiff engaged with healthcare professionals and customers, provided them with medical and scientific data and information, and facilitated opportunities for clinical research. The MSM position did not involve sales responsibilities. Abbott instructed its MSMs that they could proactively engage healthcare professionals and customers in discussions about on-label clinic data updates and safety and efficacy information. With certain restrictions, MSMs could also respond to bona fide unsolicited requests from healthcare professionals and customers for off-label information.

Plaintiff was supervised directly by Colleen Baird, the national manager for medical science/medical affairs, and indirectly by Dr. Krishna Sudhir, a divisional vice president, and Dr. Charles Simonton, the chief medical officer. Plaintiff received positive feedback, as well as cash bonuses, for multiple projects she undertook during her employment at Abbott.

In the summer of 2012, Abbott's Office of Ethics and Compliance ("OEC") investigated Plaintiff for suspicious expense reporting. Plaintiff admitted to rounding her expenses to even numbers, which she believed was consistent with the direction she received from Abbott. During the investigation, she told the OEC that she believed someone reported her to retaliate for a transition in leadership within her department. The OEC found that Plaintiff had violated Abbott's Code of Business Conduct and issued a written warning. The warning noted that Plaintiff's "professionalism was not maintained throughout the investigational process" and that she "took on an argumentative tone, in both the interview and follow up e-mails, bordering on disrespectful." Dkt. No. 161-2 at 2.

II. Plaintiff's Internal Complaints

Throughout 2012 and 2013, Plaintiff raised concerns about what she perceived to be three legal and ethical violations by her colleagues. First, in late October 2012, Plaintiff spoke with Dr. Sudhir about the relationship between Dr. Simonton and an outside physician. Plaintiff told Dr. Sudhir that Dr. Simonton was being very "aggressive" and "pushy" and that the physician was uncomfortable with their interactions. Elliott-Lewis Dep. 19:10-20:7. Plaintiff believed Dr. Simonton "seemed to be offering things in exchange for trying to get [the physician] to change his research conclusions[.]" Id. at 131:4-

24. In the email exchange that prompted Plaintiff's concern, Dr. Simonton critiques the physician's research findings and then suggests the physician may want to collaborate further with Abbott's clinical team to analyze data held by Abbott.

Second, in 2013, Plaintiff expressed concerns to Baird about a presentation Baird was developing regarding a new product called Absorb, a coronary stent. Because Absorb was not FDA-approved at the time, Plaintiff was concerned the presentation would have a promotional tone and include statements about the product's safety and efficacy. Plaintiff explained that company policy did not permit pre-approval promotion. It is unclear from the record whether anyone at Abbott ever delivered this presentation.

Third, Plaintiff spoke to Regina Deible, a new MSM hire who had previously worked at Johns Hopkins University, about a presentation she made about Absorb at a continuing medical education ("CME") conference in Las Vegas in October 2013. Plaintiff expressed concern that Deible's presentation suggested she was still affiliated with Johns Hopkins with no financial relationships to disclose and that the presentation included pre-approval promotional content. Plaintiff believed Deible's presentation also violated Abbott's policies because Abbott was sponsoring the conference and MSMs were not supposed to give

presentations or distribute printed materials at CME events sponsored by the company.

III. 2013 Performance Review

In December 2013, Plaintiff's supervisors discussed laying her off as part of a reduction in force. They acknowledged she was "coming up to speed and has real talents for the team that are different than the others" but also observed that she "struggle[s] in clinical/cath lab settings" and wondered if she was "the right fit." Dkt. No. 161, Ex. 8 at 2. On January 11, 2014, Dr. Sudhir determined that Plaintiff should only get 75% of her achievable performance bonus for 2013, the only employee in the group to get less than 100%.

Baird solicited feedback from Plaintiff's other supervisors in January 2014 in connection with her 2013 performance review. Plaintiff received positive feedback for certain projects she undertook during the previous year. However, Dr. Simonton questioned her "relationship-building capabilities," which he believed to be a "core skill" for the job. Dr. Sudhir noted "the strong perception [at headquarters] that she may not be the right person for this role, from points of view of both personality as well as educational background and interests" and that she might be "a better fit for a career in device development rather than medical affairs." Dkt. No. 161-2 at 17. In her summary, Baird wrote that the "feedback received has been

mixed, and growth areas were identified." Id. at 21. While she praised Plaintiff's work ethic and knowledge, she noted that Plaintiff was sometimes "confrontational, insular and inflexible" and might "work[] better as an individual contributor, rather than truly as a team player." Id.

Baird planned to discuss the performance review with Plaintiff during a prescheduled trip together on February 12, 2014. However, because Baird was still finishing the review, the two did not have their formal evaluation meeting that day. Baird did express to Plaintiff some of her concerns about her performance. Plaintiff told Baird that she believed she received negative feedback because Dr. Simonton wanted Deible, the new hire from Johns Hopkins, to have her job due to her better social relationships with physicians. Although she did not say this to Baird, Plaintiff believed that her supervisors wanted someone who could more easily speak with doctors about off-label marketing and pre-approval promotion. Plaintiff told Baird that, if social relationships were so important for the job, she should not have been hired in the first place and asked to be laid off to allow her to escape her noncompetition agreement and find another job. According to Baird, Plaintiff "became combative and confrontational," "told [Baird] she did not think she was a good fit" for the job, and "asked to be laid off." Dkt. No. 161-1 at 3-4.

IV. Compliance Report and Investigation

The day after Baird and Plaintiff's meeting, on February 13, 2014, Plaintiff filed a compliance report with the OEC, saying she had been "harassed" by Dr. Simonton, Dr. Sudhir, and Baird starting with the expense reporting investigation in June 2012. She stated in her report that she thought her managers were assigning projects within her territory to Deible and excluding her from trainings. Plaintiff believed her supervisors were trying to push her out because she refused to participate in unlawful marketing, namely pre-approval promotion of Absorb and off-label promotion of Xience, another coronary stent, but could not recall whether she mentioned this in her report. Her report also included her concerns about the relationship between Dr. Simonton and the outside physician and included an email exchange between the two as supporting evidence.

The OEC opened an investigation and assigned James Curcio, an employee relations manager within the human resources department ("HR"), to communicate with Plaintiff about her harassment claim. Curcio and Plaintiff met for the first time on February 24. Curcio and Plaintiff exchanged numerous communications over the next few weeks about Plaintiff's allegations that her supervisors were harassing and trying to replace her. After Baird sent Plaintiff her final performance evaluation on February 27, for example, Plaintiff told Curcio

that she thought the evaluation's "tone ha[d] been altered to be especially negative in response to [her] retaliation/harassment complaint." Elliott-Lewis Dep. 93:4-18. Curcio arranged a call with Plaintiff, Baird, and Dr. Sudhir to discuss her performance evaluation and expectations going forward. After the call, Plaintiff expressed frustration with the way Baird and Dr. Sudhir were managing her workload and the duties within her territory.

On March 2, Plaintiff emailed Curcio about what she called "key events surrounding Abbott Vascular's evolving tolerance for noncompliance in the form of medical device off-label promotion (reference Code of Federal Regulations under 21CFR812.7) and pre-approval promotion (reference Code of Federal Regulations under 21CFR801.4)."[1] Dkt. No. 161-3 at 46. Plaintiff explained that Dr. Simonton encouraged her and other MSMs to "proactively discuss off-label topics" with physicians to increase revenue for the division. Id. at 47. She also expressed concern that no one had reached out to her about these allegations. Id.

[1] Plaintiffs' citations should be reversed: 21 C.F.R. § 812.7 provides in relevant part that "[a] sponsor, investigator, or any person acting for or on behalf of a sponsor or investigator" cannot "[p]romote or test market an investigational device" prior to FDA approval, while 21 C.F.R. § 801.4 provides in relevant part that if "a manufacturer objectively intends that a device . . . is to be used for conditions, purposes, or uses other than ones for which it has been approved, . . . [the manufacturer] is required . . . to provide for such device adequate labeling that accords with such other intended uses."

On March 4, Curcio told Plaintiff that Abbott had assigned Peter Schutzel to investigate her allegations of regulatory violations. Over the next few weeks, Plaintiff emailed Curcio and Schutzel about these allegations, including that she believed Deible's presentation at the CME conference violated company policy.

V. Leave of Absence and Termination

Plaintiff began to experience physical symptoms from the stress of her dispute with her managers, including difficulty sleeping, loss of appetite, and a cough. On March 12, Plaintiff emailed Baird about her medical issues and explained that she was seeking help from a mental health professional and would be unavailable for a few days. Baird expressed concern about Plaintiff's health and asked her to contact the Leave Center to request formal medical leave if she was going to be out for more than five days. Plaintiff returned to work for only one day on March 19. She applied for medical leave on March 21 to begin on March 24. Her doctor submitted a medical certification stating that she could return to work by May 1 or earlier if she felt well.

While Matrix, an independent claims administrator, was evaluating Plaintiff's medical leave request, Plaintiff noticed that Abbott updated the performance goals listed on her profile in its employment management system. The new goal read as

follows: “Increase Absorb’s penetration into the PCI [percutaneous coronary intervention] market (Achieve Plan Revenue).” Dkt. No. 163, Ex. 56. Plaintiff believed this goal was improper because Absorb was not FDA-approved and she was not supposed to engage in pre-approval promotion in her role as an MSM. She did not speak to any of her managers about this concern. According to Baird, this performance goal was company-wide, focused on promoting Absorb in international markets where it had already been approved, and did not apply to Plaintiff or other MSMs. Baird cited an email from March 2014 in which she proposed the “penetration” goal be replaced for the MSM team with a goal to “Achieve 12 interactions at Absorb III and Absorb IV sites to support study awareness.” Dkt. No. 161-1 at 3-4.

Matrix denied Plaintiff’s medical leave request on April 21 because the certification from her doctor did not contain objective medical evidence supporting an inability to work. Matrix informed Plaintiff it would reconsider the denial if she provided additional medical evidence. Nevertheless, Rena Jacobsen, an HR specialist at Abbott, was able to approve Plaintiff for family leave on April 23, retroactive to March 24 and effective through May 1 -- the date the doctor said she could return to work. Pursuant to Abbott’s policy, Plaintiff was paid for the first forty hours of her family leave but not for the rest.

The next day, Plaintiff, who apparently had not received notice of her approval for family leave, emailed Jacobsen about the denial of her medical leave request. Plaintiff explained that she requested leave due to her stress from Abbott's failure to address her compliance report and the retaliation she suffered from management because of her opposition to engaging in illegal activity. She stated that she had not resigned her position but could not work for a company that required her to engage in illegal conduct. She asked whether Abbott had terminated her.

Plaintiff repeated these same allegations and questions in another email on April 30 to Jacobsen, on which Curcio was copied, specifically mentioning that her compliance report raised "definitive evidence of an egregious, company-supported federal False Claims Act and Anti-Kickback Statute violation." Dkt. No. 161, Ex. 32 at 7. She asked Jacobsen to issue back pay and place her on "paid leave" until the company concluded its investigation. Plaintiff testified that her reference to "paid leave" was a request to use paid vacation days, but she did not use the word "vacation" in her email. She also stated in her email to Jacobsen that she could "not return to work for managers who have made performing illegal acts a condition of [her] employment." Id. Jacobsen explained to Plaintiff that she was communicating with her about her medical leave and did not

know anything about her allegations regarding the company's marketing practices. She informed Plaintiff that, except for the first forty hours, her leave was unpaid and she was expected to return on May 2 unless she submitted an updated medical certification from her doctor.

On May 2, Plaintiff informed Jacobsen that she believed Abbott's decision not to pay her during her leave was unlawful retaliation for her compliance report. She again asked Jacobsen to issue back pay and place her on paid leave until the company concluded its internal investigation. She wrote that "the type of paid leave, for me, is irrelevant." Id. at 5.

Plaintiff did not return to work on May 2 or submit additional medical evidence to support an extension of her leave. Curcio emailed her on May 6 with three options: 1) return to work, 2) submit her letter of resignation, or 3) submit additional medical documentation. Plaintiff responded two days later repeating that she could not "return to work for managers who have made performing illegal acts a condition of [her] employment" and asking for written confirmation that Abbott had terminated her. Id. at 3-4. Curcio replied that he was interpreting her email as a resignation and would notify her manager that her employment was terminated effective May 9.

On May 12, Plaintiff explained to Curcio that she had accrued 120 hours of vacation time before her termination that

the company had not allowed her to use when her family leave ended. She wrote that she attended a doctor's appointment on May 8 but was terminated before she could provide additional medical documentation. Curcio responded that her remaining vacation days would be paid out as a lump-sum.

VI. Procedural History

Plaintiff filed a sealed qui tam complaint against Abbott on August 12, 2014. In her capacity as relator, she brought claims on behalf of the United States for violations of the FCA (Count I) and AKS (Count II). She also alleged on her own behalf that her termination was unlawful retaliation under the FCA (Count III). The United States declined to intervene.

On March 28, 2016, the court (Talwani, J.) allowed Abbott's motion to dismiss all three counts. See Elliott-Lewis v. Abbott Labs., Inc., No. 14-cv-13155, 2016 WL 9244128, at *5 (D. Mass. Mar. 28, 2016). The court dismissed the FCA claim because, while Plaintiff alleged that Abbott engaged in illegal off-label marketing and pre-approval promotion of Absorb and Xience, she failed to plead any specific false claims to the Government that resulted from this illegal conduct. Id. at *2-3. Similarly, the court dismissed the AKS count because Plaintiff did not allege any specific false claims or illegal remuneration paid to physicians. Id. at *4. Finally, the court dismissed the FCA retaliation claim because the complaint did not allege that

Plaintiff engaged in protected activity, as the concerns she raised did not involve claims for payment and thus could not reasonably have led to an FCA action. Id. at *4-5.

After some procedural maneuvering not relevant to the motions at issue, including an aborted appeal of the dismissal order to the First Circuit, Plaintiff moved for leave to amend. In addition to the three counts in the original complaint, the proposed amended complaint added a claim for wrongful termination in violation of public policy (Count IV).

On May 5, 2017, the court denied Plaintiff's motion to amend as to Counts I and II (the FCA and AKS claims) but allowed the motion as to Counts III and IV (the FCA retaliation and wrongful termination claims). See Elliott-Lewis v. Abbott Labs., Inc., No. 14-cv-13155, 2017 WL 1826627, at *7 (D. Mass. May 5, 2017). Plaintiff's proposed amended complaint alleged two FCA theories. First, she claimed that Abbott's pre-approval promotion of Absorb for use in the heart and leg was tantamount to unapproved clinic trials that violated federal human subject protection regulations, compliance with which is a precondition for Medicare's payment of routine clinical trial costs. Id. at *2. The court found this theory futile because Plaintiff failed to allege that any physician actually implanted Absorb into a leg, did not list any claim submitted to Medicare based on implantation into a leg, and the regulations Plaintiff alleged

Abbott violated were not actually preconditions to Medicare payments (so she did not allege causation). Id. at *2-4. Second, Plaintiff alleged that Abbott promoted Xience for off-label use in patients with diabetes mellitus. Id. at *4. The court also found this theory futile because the complaint did not allege any causal link between the promotional materials Abbott distributed to physicians and any decision by those physicians to use an Xience stent to treat a diabetic patient and did not explain why this off-label use was not reasonable and necessary. Id. at *4-5.

As to Count II, the AKS claim, the court held that the proposed amended complaint, like the original complaint, failed to allege any form of remuneration paid to physicians or any specific false claims submitted as a result of that renumeration. Id. at *5. On the other hand, the court determined that Plaintiff's amendments to her FCA retaliation and wrongful terminations claims were not futile because she pled that she raised internal complaints that specifically alleged FCA violations involving activities with which she had first-hand experience and regulatory violations she in good faith believed were criminal. Id. at *5-7.

Abbott moved to dismiss Count IV on the basis that the wrongful termination claim was duplicative of her FCA retaliation claim. See Elliott-Lewis v. Abbott Labs., Inc., No.

14-cv-13155, 2018 WL 1122359, at *1. The court denied the motion to dismiss, explaining that, while the FCA retaliation claim related to reporting false or fraudulent claims for payment from the United States, the wrongful termination claim included allegations that she was discharged for raising concerns about public welfare relating to off-label and pre-approval promotion of the stents. Id. at *1-2.

On August 13, 2018, Plaintiff's attorney moved to withdraw from the case, citing "a significant difference of opinion in the manner in which this case should be handled, and to a deterioration in the attorney-client relationship." Dkt. No. 104 at 1. The court allowed him to withdraw and temporarily stayed the case to allow Plaintiff to find a new lawyer. Plaintiff was unable to secure new counsel, and the Court denied her motion to enter final judgment on her qui tam claims to allow her to file an appeal. After discovery and transfer of the case to this Court, the parties filed cross-motions for summary judgment on the FCA retaliation and wrongful terminations claims.

DISCUSSION

I. Summary Judgment Standard

Summary judgment is appropriate when there is "no genuine issue as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). A genuine issue exists where the evidence "is such that a reasonable jury

could resolve the point in the favor of the non-moving party." Rivera-Rivera v. Medina & Medina, Inc., 898 F.3d 77, 87 (1st Cir. 2018) (quoting Cherkaoui v. City of Quincy, 877 F.3d 14, 23-24 (1st Cir. 2017)). A material fact is one with the "potential of changing a case's outcome." Doe v. Trs. of Bos. Coll., 892 F.3d 67, 79 (1st Cir. 2018). "The court must view the facts in the light most favorable to the non-moving party and draw all reasonable inferences in [its] favor." Carlson v. Univ. of New Eng., 899 F.3d 36, 43 (1st Cir. 2018). When the parties cross-move for summary judgment, the court must evaluate each motion "separately, drawing inferences against each movant in turn." Lawless v. Steward Health Care Sys., LLC, 894 F.3d 9, 21 (1st Cir. 2018) (quoting EEOC v. Steamship Clerks Union, 48 F.3d 594, 603 n.8 (1st Cir. 1995)).

The burden on a summary judgment motion first falls on the movant to identify "the portions of the pleadings, depositions, answers to interrogatories, admissions, and affidavits, if any, that demonstrate the absence of any genuine issue of material fact." Irobe v. U.S. Dep't of Agric., 890 F.3d 371, 377 (1st Cir. 2018) (quoting Borges ex rel. S.M.B.W. v. Serrano-Isern, 605 F.3d 1, 5 (1st Cir. 2010)). If the movant meets this "modest threshold," the burden shifts to the non-movant to "point to materials of evidentiary quality" to demonstrate that the trier of fact could reasonably resolve the issue in its favor. Id. The

court must deny summary judgment if the non-movant "adduces competent evidence demonstrating the existence of a genuine dispute about a material fact." Theriault v. Genesis HealthCare LLC, 890 F.3d 342, 348 (1st Cir. 2018).

II. Abbott's Motion for Summary Judgment

A. FCA Retaliation (Count III)

1. Legal Standard

The FCA imposes civil liability on anyone who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval" to the federal government. 31 U.S.C. § 3729(a)(1)(A). The FCA also "bars an employer from retaliating against an employee 'because of lawful acts done . . . in furtherance of an [FCA action] or other efforts to stop 1 or more violations of [the FCA].'" Guilfoile v. Shields, 913 F.3d 178, 187 (1st Cir. 2019) (second alteration added) (quoting 31 U.S.C. § 3730(h)(1)). This anti-retaliation provision aims "to prevent companies from discouraging potential relators from coming forward." Harrington v. Aggregate Indus. Ne. Region, Inc., 668 F.3d 25, 30 (1st Cir. 2012). A successful FCA retaliation claim requires proof "that 1) the employee's conduct was protected under the FCA; 2) the employer knew that the employee was engaged in such conduct; and 3) the employer discharged or discriminated against the employee because of his or her protected conduct." Guilfoile, 913 F.3d at 187-88

(quoting United States ex rel. Karvelas v. Melrose-Wakefield Hosp., 360 F.3d 220, 235 (1st Cir. 2004)).

Protected conduct includes any activity "that 'reasonably could lead' to an FCA action," such as "investigations, inquiries, testimonies or other activities that concern the employer's knowing submission of false or fraudulent claims for payment to the government." United States ex rel. Booker v. Pfizer, Inc., 847 F.3d 52, 59 (1st Cir. 2017) (quoting Karvelas, 360 F.3d at 237). While "the question of whether the employer engaged in conduct that could run afoul of the FCA is a necessary component of this inquiry," the plaintiff need not prove that the employer actually violated the FCA. See Guilfoile, 913 F.3d at 188 & n.9 (emphasis omitted). The conduct the plaintiff objects to or reports, however, must relate to the submission of false claims. See Booker, 847 F.3d at 60. Accordingly, when a plaintiff's FCA retaliation claim is based on a contractual, regulatory, or statutory violation, she must provide some reasonable basis for believing that the violation caused the submission of false claims and was material to the payment of any claims. See Guilfoile, 913 F.3d at 194-95 & n.18.

The employer knowledge prong requires that the plaintiff's protected conduct put the employer on notice of "a reasonable possibility" of FCA litigation. Maturi v. McLaughlin Research Corp., 413 F.3d 166, 173 (1st Cir. 2005). While "the employer

need not know that the employee has filed or plans to file a qui tam action," it must be aware "that the plaintiff is engaged in protected conduct." Karvelas, 360 F.3d at 238-39. As to the third element, the First Circuit has assumed without deciding that a plaintiff must show that his protected activity was the but-for cause of an adverse employment action. See United States ex rel. Hamrick v. GlaxoSmithKline LLC, 814 F.3d 10, 18 (1st Cir. 2016).

In evaluating FCA retaliation claims on summary judgment where there is no direct evidence that the employer retaliated against the plaintiff due to her protected conduct, courts employ the familiar McDonnell Douglas burden-shifting framework. See Harrington, 668 F.3d at 31. Under this framework, the "plaintiff first must set forth a prima facie case of retaliation." Id. If the plaintiff clears that "low bar," the burden of production shifts to the employer "to articulate a legitimate, nonretaliatory reason for the adverse employment action." Id. at 31-32. Once the employer has articulated a legitimate, nonretaliatory justification, "the plaintiff must assume the further burden of showing that the proffered reason is a pretext calculated to mask retaliation." Id. at 31. At the third and final step, a court "looks to the record as a whole to determine whether there is sufficient evidence of 'pretext and retaliatory animus' . . . to create a genuine issue as to

whether retaliation was the real motive." Id. (quoting Mesnick v. Gen. Elec. Co., 950 F.2d 816, 827 (1st Cir. 1991)).

2. Analysis

Abbott argues that Plaintiff cannot show that she engaged in protected conduct under the FCA because there is no reasonable connection between the conduct about which she complained and the submission of false claims within the purview of the FCA. Plaintiff raised a host of concerns about Abbott's conduct throughout her employment with the company. Most involved what she considered harassment from her supervisors and violations of company policy by Baird, Deible, and others, which had nothing to do with the submission of false claims to the Government and are therefore not protected conduct.

Plaintiff contends that she engaged in protected conduct when she filed her compliance report and followed up with Curcio and Schutzel with concerns that Abbott was engaging in pre-approval promotion of Absorb and off-label marketing of Xience in violation of federal regulations. This argument is foreclosed by the First Circuit's decision in Booker. See 847 F.3d at 60. There, the court reasoned that "[e]vidence that an employee objected to or reported receipt of instructions to promote a drug's off-label use, absent any evidence that those objections or reports concerned FCA-violating activity such as the submission of false claims, cannot show at the summary judgment

stage that the employee engaged in conduct protected by the FCA." Id. Even if a plaintiff complains about violations of regulations that are a requirement for reimbursement by Medicare and Medicaid, such violations are "not actionable under the FCA in the absence of actual fraudulent conduct," and reporting such violations falls "outside the purview of the FCA's anti-retaliation provision." Id.

Plaintiff's concerns focused exclusively on the company's alleged violations of company policies and federal regulations, not on the fraudulent submission of claims to the Government. While the "law does not require a plaintiff to connect all of the dots between alleged [regulatory violations] and fraud on the government," United States ex rel. Lokosky v. Acclarent, Inc., 270 F. Supp. 3d 526, 533 (D. Mass. 2017), "there must be a reasonable connection between the alleged conduct and the submission of claims within the purview of the FCA." Guilfoile, 913 F.3d at 195.

Plaintiff's theories of how the misconduct she reported led to the submission of false claims are too attenuated to transform her complaints about regulatory violations into protected conduct under the FCA. For Xience, Plaintiff claims that Dr. Simonton improperly pressured a physician to change his research conclusions and that Abbott then used his research to promote Xience off-label for diabetes patients, which caused the

submission of false claims. For Absorb, Plaintiff raises two theories. First, she rehashes an argument the court found failed to state a substantive claim under the FCA: that Abbott was promoting Absorb for use in the leg even though it was only approved for clinical trials in the heart. Second, she claims that Abbott improperly promoted Absorb to doctors before it received FDA approval, including through Deible's 2013 CME presentation and the directive Plaintiff alleges she received to "[i]ncrease Absorb's penetration into the PCI market (Achieve Plan Revenue)."

Plaintiff has not shown any violations of the FCA. For example, there is no evidence the physician actually changed his results in response to Dr. Simonton's pressure or that Abbott used his allegedly falsified research in its marketing materials for Xience. Nor does Plaintiff show any connection between the alleged unlawful pre-approval marketing of Absorb and the submission of false claims to the Government.

In sum, Plaintiff has not established that she engaged in protected conduct under the FCA because she complained primarily about her relationship with her managers, violations of company policy, and regulatory violations that have an unlikely connection to the submission of fraudulent claims to the Government. Abbott is therefore entitled to summary judgment on Count III, and the Court need not address the parties' arguments

concerning the other elements of an FCA retaliation claim or the other steps of the McDonnell Douglas burden-shifting framework.

B. Wrongful Termination in Violation of Public Policy (Count IV)

1. Legal Standard

"The baseline common law rule in Massachusetts is that an employer may lawfully terminate a relationship with an at-will employee at any time – for any reason, for no reason, and even for a reason that might be seen by some as unwise or unkind." Murray v. Warren Pumps, LLC, 821 F.3d 77, 89 (1st Cir. 2016). Massachusetts law recognizes an exception to this rule to "protect[] at-will employees from terminations that conflict with sufficiently important and clearly defined public policies." Id. Courts interpret this public policy exception narrowly to avoid altering the baseline rule of at-will employment. Barbuto v. Advantage Sales & Mktg., LLC, 78 N.E.3d 37, 50 (Mass. 2017). The dispositive question "is whether a well-established public policy is served by denying the employer the right freely to discharge an employee for engaging in particular conduct." Shea v. Emmanuel Coll., 682 N.E.2d 1348, 1349 (Mass. 1997). Whether discharging an at-will employee for engaging in particular conduct violates public policy is a question of law for the court, and an at-will employee bears the burden of showing that it does. Murray, 821 F.3d at 90.

Massachusetts courts have delineated three categories of justifications for termination of an at-will employee that violate public policy: 1) "asserting a legally guaranteed right (e.g., filing workers' compensation claim)"; 2) "doing what the law requires (e.g., serving on a jury)"; and 3) "refusing to do that which the law forbids (e.g., committing perjury)." Id. at 89 (quoting Smith-Pfeffer v. Superintendent of the Walter E. Fernald State Sch., 533 N.E.2d 1368, 1371 (Mass. 1989)). An employee may also recover if she is terminated for performing certain important public deeds not strictly required by the law. Id. For example, employees are protected from discharge when they make "an internal complaint . . . about the alleged violation of the criminal law." Shea, 682 N.E.2d at 1350. They are also protected when they "report, resist, or refuse to participate in activity that presents a threat to public health or safety," Surprise v. Innovation Grp., Inc./First Notice Sys., Inc., 925 F. Supp. 2d 134, 148 (D. Mass. 2013). "[T]he alleged harm or threat to health and safety must not be too remote or speculative." Acher v. Fujitsu Network Commc'ns, Inc., 354 F. Supp. 2d 26, 30 (D. Mass. 2005). On the other hand, "the public policy exception does not protect at-will employees from termination for performing generally socially desirable duties or for raising workplace complaints about internal company matters." Murray, 821 F.3d at 89-90. "Nor

does it extend so far as to cover all acts by an employee that are directed to illegal, unsafe, or unethical conduct." Surprise, 925 F. Supp. 2d at 148.

2. Analysis

Abbott seeks summary judgment on Plaintiff's wrongful termination claim on the basis that her internal reporting does not implicate a sufficiently important public policy to justify an exception to the at-will employment rule. Plaintiff's reporting of harassment from her supervisors and alleged violations of company policy largely concerned internal matters and are not protected activity for the purposes of a wrongful termination claim. See Murray, 821 F.3d at 89-90.

Plaintiff points to her internal reporting of pre-approval promotion and off-label marketing activities in violation of federal regulations. Internal reporting of alleged violations of federal regulations intended to protect public health and safety, such as those forbidding off-label marketing and pre-approval promotion, implicate a sufficiently important public policy and constitute protected activity. See Mercado v. Manny's T.V. & Appliance, Inc., 928 N.E.2d 979, 984-85 (Mass. App. Ct. 2010) (finding protected activity where the plaintiff objected to conduct that violated state statutes intended to "protect public health, safety, and welfare"); see also Murray, 821 F.3d at 90 (explaining that termination "for refusing to participate

in unlawful or deceptive conduct that directly compromise[s] public safety" violates the public policy of Massachusetts).

When all reasonable inferences are drawn in Plaintiff's favor, the record contains sufficient evidence for a jury to conclude that she raised specific concerns about off-label marketing of Xience and pre-approval promotion of Absorb. On March 2, 2014, she emailed Curcio about what she called "key events surrounding Abbott Vascular's evolving tolerance for noncompliance in the form of medical device off-label promotion . . . and pre-approval promotion[.]" Dkt. No. 161-3 at 46. She explained that Dr. Simonton encouraged her and other MSMs to "proactively discuss off-label topics" with physicians to increase revenue for the division. Id. at 47. Separately, she told Curcio and Schutzel around the same time about Deible's presentation on Absorb at the CME conference.

Abbott argues that Plaintiff has not provided any evidence that Abbott terminated her because of this reporting. See Robert Reiser & Co. v. Scriven, 130 F. Supp. 3d 488, 497 (D. Mass. 2015) (explaining that a plaintiff raising a wrongful termination claim must "present evidence of a causal connection between the protected activity and adverse employment action"). Abbott has submitted an affidavit from Curcio, the ultimate decisionmaker for Plaintiff's termination, in which he explains that he terminated Plaintiff because she did not return to work

after her approved leave of absence ended or submit additional medical documentation to justify an extension.

Plaintiff does not dispute that she was asked to submit "an updated medical certification form" to extend her leave past May 1, 2014 and was told that if she did not produce the requested form or return to work, her continued absence would be "recognized as a resignation." Dkt. No. 161 ¶ 31, 38; Dkt. No. 169 ¶ 31, 38. Nor does Plaintiff dispute that she did not submit that form.

Under these circumstances, no reasonable jury could conclude that Plaintiff's accusations of wrongdoing were the cause of her termination. While temporal proximity between protected activity and the adverse employment decision can in some circumstances support a claim of wrongful termination, it is not dispositive. Strong evidence of a legitimate basis for termination can outweigh even close temporal proximity. See Straughn v. Delta Air Lines, Inc., 250 F.3d 23, 45 (1st Cir. 2001) (finding no triable issue of fact in wrongful discharge case under New Hampshire law where "mere temporal proximity . . . pale[d] to insignificance against the overwhelming weight of the evidence underpinning the plainly legitimate rationale for the discharge decision by [the employer]").

Curcio made clear that Plaintiff could retain her employment by either returning to work as an MSM or submitting a

medical certification from her physician to extend her leave. Plaintiff chose not to take either action. Where Plaintiff was offered an opportunity to continue her employment and declined to pursue it, her protected activity cannot be said to have caused her termination. She explains that she did not return because she refused to engage in potentially unlawful acts set forth in her performance goals to increase Absorb's penetration into the PCI Market prior to approval. She received this performance goal in April 2014 while she was on FMLA leave. She alleges this was an illegal directive. Abbott argues that the goal did not apply to MSMs, who instead had a goal related to "study awareness." Even if the goal was improperly given to Plaintiff, there is no evidence that she informed anyone at Abbott that she was refusing to return because of this goal. Accordingly, there is no reasonable inference that Abbott gave her its ultimatum as a pretext for her refusal to engage in unlawful acts. The undisputed evidence is that her employment ended because she refused to return to work.

Plaintiff has not raised the issue of constructive discharge. However, because she proceeds pro se, I examine the issue. The doctrine of constructive discharge prevents an employer from escaping liability for wrongful discharge through "a calculated effort to pressure [Plaintiff] into resignation through the imposition of unreasonably harsh conditions."

Calhoun v. Acme Cleveland Corp., 798 F.2d 559, 561 (1st Cir. 1986) (quotation omitted). Even accepting Plaintiff's claim that she was asked to follow an illegal directive, the Court concludes there is no evidence Abbott tried to pressure Plaintiff to resign. Nor was Plaintiff otherwise subjected to "working conditions . . . so onerous, abusive, or unpleasant that a reasonable person in the employee's position would have felt compelled to resign." Suarez v. Pueblo Int'l, Inc., 229 F.3d 49, 54 (1st Cir. 2000).

Abbott is entitled to summary judgment on Count IV because Plaintiff has failed to show a causal connection between her allegations of wrongdoing and her termination.

III. Plaintiff's Motion for Summary Judgment

Plaintiff also moves for summary judgment on both her FCA retaliation and wrongful termination claims. Abbott asks the Court not to consider the motion because Plaintiff filed it a week after the deadline set in the scheduling order, but the Court need not address the timeliness of the motion. For the reasons described above, Abbott is entitled to judgment as a matter of law on the FCA retaliation claim because there is no evidence Plaintiff engaged in protected conduct. Abbott is also entitled to judgment as a matter of law on the wrongful termination claim because no reasonable jury could conclude that Plaintiff's protected activity was the cause of her termination.

ORDER

Accordingly, Abbott's motion for summary judgment (Docket No. 159) is **ALLOWED**, and Plaintiff's motion for summary judgment (Docket No. 164) is **DENIED**.

SO ORDERED.

/s/ PATTI B. SARIS
Hon. Patti B. Saris
Chief United States District Judge